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Food and Agricultural Import Regulations and Standards

Maximum Levels for Vitamins and Minerals

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Approved by:
Debra Henke
U.S. Mission to the EU

Prepared by:
Hilde Brans / Jennifer Kane (DOC)

Report Highlights:
In November 2006, responses to the EU's Discussion Paper on the setting of minimum and maximum levels for nutrients in food supplements and fortified foods were presented at a conference organized by the EU food supplements industry. The new regulation on fortified foods was only recently notified to the WTO and third countries have until January 18, 2007, to submit comments.

Includes PSD Changes: No
Includes Trade Matrix: No
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[E3]

Maximum Levels for Vitamins and Minerals

The EU's food supplements directive (2002/46/EC) provides for the establishment of maximum levels for vitamins and minerals. Similar provisions are contained in the yet to be published regulation on fortified foods (ref GAIN report E36087). Within two years of the regulation's entry into force, the Commission must submit a proposal on minimum and maximum levels of vitamins and minerals to enrich foods. Proposed levels for both the food supplements directive and the new regulation on fortified foods will have to be adopted as an implementing measure by the Member States through the new comitology procedure. The new comitology procedure puts the European Parliament (EP) on equal footing with the Council, which means that the EP can now also block draft implementation measures.

Although the proposal for a regulation on fortified foods was published in 2003 and adopted in October 2006, the EU only notified this new measure to the WTO on December 11, 2006 (notification G/TBT/N/EEC/138). Third countries can submit comments within 30 days, i.e. until January 18, 2007. These comments may be taken into account in a future revision of the yet to be published regulation (expected early 2007).

In June 2006, the European Commission launched an online discussion paper inviting input from stakeholders on the setting of minimum and maximum levels of vitamins and minerals. The consultation closed on September 30, 2006, and the responses to the EU's discussion paper were presented at a conference organized by the EU food supplements industry. The Commission received 58 contributions from EU member states, third countries including the U.S., trade associations, and manufacturers. Responses can be downloaded from the Commission's website at http://ec.europa.eu/food/food/labellingnutrition/supplements/resp_discus_paper_amount_vitamins.htm.

At the conference, responses to the EU's discussion paper were outlined as follows:

- Question 1: What should the upper level be when no scientifically established upper level is available?
Some respondents suggested a case-by-case approach to set maximum levels, others suggested that there is no need to establish a UL when no adverse effects are found at high doses or to use data from organizations such as the U.K. Export Group of Vitamins and Minerals or the WHO/FAO.

- Question 2: Should maximum levels be set for low-risk nutrient?
Respondents called for a case-by-case approach for all nutrients as the absence of EU-wide maximum levels could lead to member states setting their own levels, which would distort trade. Most agreed on what the low-risk nutrients are (vitamins B1, B2 and B12, biotin, pantothenic acid) except for Vitamin K and Chromium III.

- Question 3: Do separate maximum amounts have to be set for food supplements and fortified foods?
Views varied suggesting that maximum levels should be set for both supplements and foods or to use a case-by-case approach and set separate maximum levels only when there is a risk of exceeding upper levels.

- Question 4: Which sources provide the best intake data?
Most member states referenced their own data while other member states referenced the U.K.'s National Diet and Nutrition Survey as an excellent source of useful data. DG Sanco reacted that national surveys should not be compared because of different methodologies to collect and analyze data.

- Question 5: Can national intake data be used to set EU-wide maximum levels?
Most respondents agreed that national intake data should not be used with the exception of the U.K. data. Some suggested to establish national guidance levels in parallel to the EU-wide maximum levels due to the divergent national intakes.

- Question 6: Should different population groups be taken into consideration when setting maximum levels?
The majority said "NO", emphasizing that this would be confusing to consumers and burdensome for industry. There was general agreement that maximum levels should be established for adults.

- Question 7: How far should PRIs (Population Reference Intakes) / RDAs (Recommended Daily Allowances) be taken into consideration?
The majority of respondents stressed that maximum levels should be based on risk assessment, not on the nutritional need of the population.

- Question 8: Should the minimum amount in fortified foods be the same as the minimum requirement for making a claim or declaration of the nutrient in nutritional labeling?
There was general agreement that the minimum amount in fortified foods should be in principle related to the significant amounts required to be present for making a claim and/or for a declaration in the nutritional labeling.

- Question 9: Should the minimum amount in food supplements be the same as the minimum requirement for labeling purposes?
This was not a major issue for stakeholders.

Overall, there was agreement on the need to set EU-wide maximum levels for vitamins and minerals, on a classification of nutrients in different categories, and to treat food supplements and fortified foods in the same manner. Next steps will include the publication by the Commission of an "Options Paper" and to start discussions in member states working groups.

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Related reports from USEU Brussels:

Report Number	Title	Date Released
E36087	European Parliament passes new EU rules on fortified foods	5/24/2006
E36086	European Parliament passes new EU rules on nutrition and health claims	5/24/2006
These reports can be accessed through our website http://useu.usmission.gov/agri or through the FAS website http://www.fas.usda.gov/scriptsw/attacherep/default.asp.		